

EXHIBIT O

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND
COMPOUNDING PHARMACY,
INC. PRODUCTS LIABILITY MDL No. 2419
LITIGATION

Master Dkt:
1:13-md-02419-RWZ

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THIS DOCUMENT RELATES  
TO:

All Actions  
  
~~~~~

VIDEOTAPED DEPOSITION OF
KENNETH R. LISTER, M.D.

9:03 a.m.
March 9, 2015

Suite 1100
315 Deaderick Street
Nashville, Tennessee

Blanche J. Dugas, RPR, CCR No. B-2290

1 A. I presume that was a hospital financial
2 decision.

3 Q. What do you mean by that?

4 A. They made a choice to keep me where their
5 production was best.

6 Q. Are they able to receive a higher
7 reimbursement by having you do that procedure at the
8 hospital?

9 A. I think they do, yes.

10 Q. Is there a clinic within the hospital that
11 you operate out of when you do those procedures?

12 A. No.

13 Q. Do you use a hospital operating room?

14 A. Yes.

15 Q. Going back to the time when you were
16 affiliated with Specialty Surgery Center. Let's talk
17 in particular about 2012. Was Specialty Surgery
18 Center also paid some money in connection with the
19 epidural steroid injections that you performed?

20 A. Yes, it was.

21 Q. How were they paid?

22 A. I presume they were paid directly from the
23 insurance companies.

24 Q. Or from Medicare?

25 A. Or from Medicare, which is an insurance

1 company.

2 Q. And you were paid also money in connection
3 with the epidural steroid injections that you
4 performed at Specialty Surgery Center separate and
5 apart from the money that was paid to Specialty
6 Surgery Center?

7 A. Yes.

8 Q. Did you supply the steroid that was
9 injected into the patients?

10 A. No.

11 Q. Who did?

12 A. Specialty Surgery Center procured all of my
13 supplies.

14 Q. Is that part of your agreement with
15 Specialty Surgery Center?

16 A. Yes.

17 Q. Did you tell Specialty Surgery Center which
18 supplies you wanted them to procure for you?

19 A. I told them what supplies that I needed.

20 Q. How did you communicate that to Specialty
21 Surgery Center in 2012?

22 A. My communications were usually either
23 directly to Jean Atkinson.

24 Q. Did you use an e-mail in 2012?

25 A. Yes.

1 when giving steroid injections in 2012?

2 A. No.

3 Q. Did Specialty Surgery charge patients for
4 epidural steroid injections in 2012?

5 A. Are you asking did they charge for supplies
6 or are you asking did they charge for the procedure?

7 Q. Well, let's break those out. Did Specialty
8 Surgery Center charge for the procedure in 2012 for
9 epidural steroid injections?

10 A. Yes, Specialty Surgery Center did charge
11 for the procedure.

12 Q. And what do you mean when you say the
13 procedure?

14 A. The charge was an all-inclusive charge for
15 the procedure of performing the epidural steroid
16 injections.

17 Q. And that charge included the charge for the
18 steroid itself?

19 A. I presume that the charge for the steroid
20 itself was included in the overall charge for the
21 procedure.

22 Q. And so what did you charge for?

23 A. I charged simply for my services of
24 administering the epidural steroid injection.

25 Q. And Specialty Surgery charged for

1 everything other than your services?

2 A. Correct.

3 Q. Part of the money that was paid to
4 Specialty Surgery Center in 2012 was for the epidural
5 steroid itself; is that right?

6 A. The money was a global payment from the
7 insurance company.

8 Q. Was the steroid free?

9 A. The steroid was a cost to the surgery
10 center, but the money was a global payment for the
11 epidural steroid.

12 Q. You're talking about the money received
13 from either patient or some third-party payor on
14 behalf of the patient?

15 A. Correct.

16 Q. Did you receive any money in 2012 for the
17 steroid itself that was injected into the patients?

18 A. No.

19 Q. Does Specialty Surgery Center, PLLC exist
20 today?

21 A. I believe it has been dissolved.

22 Q. When did that happen?

23 A. I believe it was finally dissolved at the
24 end of last year.

25 Q. End of 2014?

1 A. Correct.

2 Q. And have you always kept current with those
3 requirements?

4 A. Yes, I have.

5 Q. Did Specialty Surgery Center in 2012
6 subscribe to any medical journals, to your knowledge?

7 A. Not to my knowledge.

8 Q. Did you read any other medical journals in
9 2012 on a regular basis?

10 A. Any other medical journals?

11 Q. Right. Other than the American Society of
12 Interventional Pain Physicians journal.

13 A. No, I did not.

14 Q. Did you -- maybe I assumed something. Did
15 you read the journal from the American Society of
16 Interventional Pain Physicians?

17 A. Yes, I did.

18 Q. Did you read every issue that came to you?

19 A. I read the majority of each issue.

20 Q. Who decided to dissolve Specialty Surgery
21 Center?

22 A. That was a partnership decision.

23 Q. Did you agree with it?

24 A. No.

25 Q. Why not?

1 Specialty Surgery Center agreed to provide medications
2 for your use in procedures including epidural
3 steroids?

4 A. No, there was not.

5 Q. So on what basis did Specialty Surgery
6 Center provide those supplies for your use?

7 A. I'm not sure of your question.

8 Q. Well, did you have some agreement with
9 Specialty Surgery Center either in writing or verbally
10 that Specialty Surgery Center would provide
11 medications including epidural steroid injection --
12 epidural steroids for epidural steroid injections?

13 A. Specialty Surgery Center provided and
14 billed for those services for the epidural steroid
15 injections.

16 Q. And that included for the epidural steroid
17 itself?

18 A. They billed for the full service.

19 Q. Okay. Well, maybe we're not understanding
20 each other. Did you have -- how did you know that --
21 when you showed up at Specialty Surgery Center to do
22 an epidural steroid injection, how did you know that
23 you didn't have to bring the steroids with you?

24 A. Because they supplied all of the
25 medications and supplies needed.

1 Q. And then they billed a third party or a
2 patient for those supplies?

3 A. Correct.

4 Q. What -- did somebody tell you -- did you
5 have some conversation with Specialty Surgery where
6 they said, don't worry, we'll supply the steroids.
7 You just show up and do your injection?

8 A. That is the standard practice of all
9 medical facilities, whereas they provide equipment,
10 supplies, personnel necessary for procedures. I have
11 no written agreement with Cumberland Medical Center or
12 any other hospital as well.

13 Q. When you do procedures at Cumberland
14 Medical Center, Cumberland Medical Center provides the
15 steroids for use in epidural steroid injections?

16 A. Correct.

17 (Exhibit 80 was marked for
18 identification.)

19 Q. (By Mr. Chalos) I'm going to hand you the
20 next numbered exhibit, No. 80. So we've marked
21 Exhibit No. 80. It's SSC-01826 through 01832. So
22 while you're looking at Exhibit No. 80, which is
23 SSC-01826 through 01832 --

24 MS. HOLLABAUGH: Mark, do you have
25 copies of that?

1 Q. Why were you involved in this phone
2 conference call?

3 A. I presume the reason I was involved was
4 because the surgery center had a large pain management
5 practice.

6 Q. So this report here says that -- looking
7 under points of discussion. You see that?

8 A. Uh-huh (affirmative).

9 Q. It says, "Relying on our management reports
10 from January 2012 to September 30th of 2012,
11 approximately 35 percent of our procedure volume is
12 through pain management services."

13 Was that true?

14 A. That was true according to this surgery
15 center records, correct.

16 Q. Where are the surgery center records today,
17 financial records?

18 A. I believe they're in Dr. Simpson's office.

19 Q. Then it goes on to say, "Looking at our
20 other management reports, this is somewhere around 85
21 to 90 cases per month."

22 Does that sound right?

23 A. That sounds reasonable.

24 Q. Then, "Our average reimbursement for those
25 cases is approximately" -- and then it's blacked out

1 there. That's a dollar amount, I assume that's
2 blacked out?

3 A. Must be.

4 Q. Then says, "This reflects Dr. Lister's work
5 almost exclusively"?

6 A. Yes.

7 Q. And of those -- we talked earlier, you said
8 you did you think about 20 to 30 procedures per week
9 about half of which were epidural steroid injections?

10 A. I believe that's a reasonable estimate.

11 Q. So do you think using their numbers here,
12 85 to 90 cases per month of pain management services,
13 do you think about half of those were epidural steroid
14 injections?

15 A. I suspect that's correct.

16 Q. And you were the only doctor at that time
17 at Specialty Surgery Center who was doing pain
18 management?

19 A. At that time, I was the only one actually
20 doing pain management.

21 Q. In 2012, what other services were being
22 done at Specialty Surgery Center?

23 A. Dr. Simpson did orthopaedic cases. Dr.
24 Pick did orthopaedic cases. Dr. Nichols did GI
25 scopes. Dr. Lee did GI scopes. Dr. Fox did general

1 MR. GIDEON: Objection to the form.

2 Q. (By Mr. Chalos) Would you bill separately
3 for the post-procedure visit?

4 A. Yes.

5 Q. Did you ever see the bills that Specialty
6 Surgery Center sent to the patient and/or patient's
7 insurance company for the epidural steroid injection?

8 A. Not that I recall.

9 Q. Have you ever -- as you sit here today,
10 have you ever seen any of their bills?

11 A. I have probably seen some, but I, again,
12 don't recall.

13 Q. Was your lease agreement with Specialty
14 Surgery Center ever revised to reflect the new
15 arrangement in 2012?

16 A. I believe it must have been, but I --
17 again, I don't recall.

18 Q. You say it must have been. Why?

19 A. Because it states so in the board minutes
20 there.

21 Q. Do you know whether the reimbursement to
22 Specialty Surgery Center for epidural steroid
23 injections changed depending on how much Specialty
24 Surgery Center paid for the steroid itself?

25 A. No.

1 Q. No, you don't know or, no, it didn't
2 change?

3 A. It didn't change.

4 Q. Okay. So however much Specialty Surgery
5 Center paid for the steroid itself, the reimbursement
6 from the insurance companies was always the same?

7 A. Correct.

8 Q. So if the amount that Specialty Surgery
9 Center paid for a steroid product were less, then
10 Specialty Surgery Center would be able to put more of
11 the reimbursement to its bottom line?

12 A. I guess that's an assumption, yes.

13 Q. Is that an accurate assumption?

14 A. It would seem reasonable.

15 Q. You disagree with that?

16 A. Yes.

17 Q. Why do you disagree?

18 A. I don't disagree. I think that's a
19 reasonable assumption.

20 Q. Is it correct?

21 A. It's correct.

22 Q. Thank you. I don't mean to quibble with
23 you. We just got to make sure this record makes
24 sense.

25 MR. CHALOS: We're probably at a good

1 A. I don't recall.

2 Q. What was said during that meeting, to the
3 best of your recollection?

4 A. To the best of my recollection, they asked
5 the -- they asked many questions regarding our
6 procurement of medications from NECC.

7 Q. Do you recall any of the specific questions
8 they asked you?

9 A. No.

10 Q. Do you recall any of the answers that you
11 gave?

12 A. No specific answers, no.

13 Q. Was there anybody else there from Specialty
14 Surgery Center?

15 A. Not that I recall.

16 Q. Was Ms. Atkinson there?

17 A. I believe they interviewed her separately.

18 Q. Did you discuss with any of the patients
19 into whom you injected NECC's MPA that the MPA came
20 from a compounding pharmacy?

21 A. No, I did not.

22 Q. Did you tell any of the patients into whom
23 you injected NECC's MPA that the product had no
24 preservatives in it?

25 A. No, I did not.

1 Q. Since this outbreak, have you ever used MPA
2 without preservatives?

3 A. I don't believe MPA is available without
4 preservative at this point in time.

5 Q. Have you -- since this outbreak, have you
6 ever used any steroid for epidural injections without
7 preservatives?

8 A. No.

9 Q. So the one and only time in your career
10 that you recall using a steroid for epidural
11 injections without preservatives was when you used the
12 MPA from NECC?

13 A. Yes.

14 Q. What role did you play in choosing to buy
15 steroids from NECC before injection into patients?

16 A. I requested from Jean to search for
17 companies that might be able to provide
18 methylprednisolone acetate preservative-free.

19 Q. Why did you do that?

20 A. I was concerned with the long-term effects
21 of picolinium ac -- picolinium as causing the
22 potential problem of severe arachnoiditis in my
23 patients.

24 Q. And what raised that concern with you?

25 A. There had been multiple case reports of

1 A. I believe there was a significant shortage
2 of MPA in the marketplace.

3 Q. Why do you believe that?

4 A. One of the major pharmaceutical companies
5 had cut down on its production.

6 Q. Which one?

7 A. I believe it was TEVA.

8 Q. And how do you know that?

9 A. I know it from discussions with my
10 attorneys.

11 Q. When did you learn that?

12 A. I learned of the shortage in 2012 because
13 we were having trouble obtaining the medication.

14 Q. Who told you in 2012 that there was a
15 shortage of MPA?

16 A. Diane Austin would do the majority of the
17 ordering at the facility. And Diane, who is one of
18 our scrub techs, came to me and said, I'll order two
19 boxes of the methyl -- of the Depo-Medrol and I'll
20 only get one.

21 Q. Was there ever a time in 2012 before this
22 outbreak that Specialty Surgery Center was unable to
23 obtain any MPA?

24 A. I don't believe there was any time that we
25 were unable to obtain any MPA.

1 Q. So the person who told you about a shortage
2 in 2012 was Diane Austin; is that right?

3 A. Correct.

4 Q. And did she tell you what steps she had
5 taken to try to locate sources for MPA?

6 A. Usually she would refer that back to Jean.

7 Q. So did you tell either Ms. Austin or
8 Ms. Atkinson that they should look for other sources
9 of MPA other than whoever was supplying at the time in
10 2012?

11 A. No.

12 Q. Who was the supplier of MPA for Specialty
13 Surgery Center prior to NECC?

14 A. I believe it was Besse or CuraScript.

15 Q. And when did you learn that? Did you know
16 it at the time or did you learn that since then?

17 A. I knew those names just off the top of my
18 head, but I don't know when I learned it.

19 Q. And the steroid that Specialty Surgery
20 Center was using prior to buying from NECC was a
21 branded Pfizer product; is that right?

22 A. I don't believe it was always a branded
23 Pfizer product. It may have been a generic product at
24 times.

25 Q. Was -- at any time before buying from NECC,

1 did Specialty Surgery Center buy steroids for epidural
2 use that were made by compounders?

3 A. While we had bought from compounders
4 before, I don't believe we had bought steroids.

5 Q. At any time after the fungal infection
6 outbreak, did Specialty Surgery Center purchase
7 steroids for epidural injection that were made by a
8 compounder?

9 A. No.

10 Q. So the one and only time that Specialty
11 Surgery Center bought steroids for epidural injection
12 made by a compounder is when they bought from NECC?

13 A. Correct.

14 Q. When did you learn that Specialty Surgery
15 Center was considering purchasing MPA
16 preservative-free from NECC?

17 A. It would have been early in July.

18 Q. And from whom did you learn that?

19 A. Jean Atkinson.

20 Q. Atkinson. Okay. What did she tell you?

21 A. Jean came to me and said, I have found a
22 source of Omnipaque in smaller vials. And I said,
23 that's good. We don't want to waste Omnipaque. She
24 said, they also have preservative-free Depo-Medrol.
25 And I said, that's good too. We can go with that

1 Q. Okay. When you injected your patients with
2 NECC's MPA, did you know that that MPA was compounded
3 by NECC?

4 A. No.

5 Q. When did you learn that the MPA that you
6 injected into your patients was actually compounded by
7 NECC?

8 A. After the meningitis outbreak.

9 Q. Did you do any research into NECC prior to
10 Specialty Surgery Center purchasing MPA from NECC?

11 A. No.

12 Q. Did you rely on Ms. Atkinson to do that
13 research?

14 A. Yes.

15 Q. Did you rely on Calisher & Associates to do
16 research before they approved the purchase of MPA from
17 NECC?

18 A. Yes.

19 Q. What is arachnoiditis?

20 A. Arachnoiditis is a severe chronic,
21 debilitating inflammation of the interior meninges
22 that causes bladder and bowel disturbance, severe gait
23 disturbance and chronic severe pain.

24 Q. Have any of the patients that you injected
25 with NECC's MPA developed arachnoiditis?

1 A. Not as far as I know.

2 Q. Did -- prior to purchasing MPA from NECC,
3 did you discuss -- prior to Specialty Surgery Center
4 purchasing -- let me start over.

5 Prior to NE -- start again.

6 Prior to Specialty Surgery Center
7 purchasing MPA from NECC, did you discuss with
8 Ms. Atkinson or anyone else other options for sourcing
9 the MPA at that time?

10 A. At that point in time, no.

11 Q. Do you know whether Ms. Atkinson considered
12 any other sources for the preservative-free MPA at
13 that time?

14 A. I do not know.

15 Q. Have you ever heard of the Pharmacy
16 Compounding Accreditation Board?

17 A. No.

18 Q. Sometimes abbreviated PK -- PCAB?

19 A. No.

20 Q. Have you ever -- prior to purchasing from
21 NECC, had you ever seen any information published by
22 the Food and Drug Administration about the dangers --
23 potential dangers of compounded drugs?

24 A. No.

25 Q. Had you seen in any media articles prior to

1 purchasing from NECC any discussion of the potential
2 dangers of compounded drugs?

3 A. No.

4 Q. Have you seen any medical literature prior
5 to purchasing from NECC regarding the potential
6 dangers of compounded drugs?

7 A. No.

8 Q. Have you had any discussions, either in
9 person, on the telephone or in writing or e-mail or
10 otherwise, with anyone affiliated with NECC?

11 A. No.

12 Q. Did you have any role in deciding how the
13 NECC compounded MPA would be stored at the Specialty
14 Surgery Center facility?

15 A. No.

16 Q. How were the vials of MPA from NECC stored
17 at the Specialty Surgery Center facility?

18 A. They were stored at room temperature.

19 Q. In what type of structure?

20 A. In the medicine cabinet, pharmaceutical
21 cabinet.

22 Q. Is there a sterile storage area at
23 Specialty Surgery Center or was there?

24 A. A sterile storage area?

25 Q. Yes, sir.

1 Q. Was it in that -- was it in the first of
2 the three conversations that you asked her to find out
3 if NECC was licensed?

4 A. Yes.

5 Q. And what kind of a license were you
6 thinking of when you asked her that?

7 A. I was thinking of a license to produce
8 medications.

9 Q. Did you ask her to find out if NECC was
10 accredited?

11 A. I asked her to find out if they were
12 licensed.

13 Q. Not accredited?

14 A. I don't know what accredited means.

15 Q. Why was the fact of the license important
16 to you?

17 A. A company that's not licensed would not be
18 a legal company and, therefore, it would not be a safe
19 company for my patients.

20 Q. And did Ms. Atkinson have the green light
21 to order drugs from NECC after she found out whether
22 or not they were licensed?

23 A. No, she did not have the green light.

24 Q. Tell me everything you remember about the
25 first conversation you had with Ms. Atkinson.

1 A. I asked her if they were licensed. I asked
2 her if she had checked with the Calishers to see if
3 they considered it appropriate to buy from NECC. I
4 asked her to -- I asked her to review their
5 literature.

6 Q. Did Ms. Atkinson follow up and tell you
7 that she determined that NECC was licensed?

8 A. Yes.

9 Q. And did she show you a copy of the license?

10 A. Yes, she did.

11 Q. Did you ask her to do any other
12 investigation of NECC besides -- the literature -- I'm
13 sorry. Withdraw.

14 Did you look at the literature that she
15 received from the NECC salesperson?

16 A. No, I did not.

17 Q. Did you ask if she -- if you could look at
18 it?

19 A. No, I did not.

20 Q. Do you know if any of the Calishers
21 reviewed the literature?

22 A. I do not know.

23 Q. Did you ask Ms. Atkinson to make sure the
24 literature goes to the Calishers so they could review
25 it?

1 pursuant to prescriptions, were they?

2 A. I'm not sure of your question.

3 Q. I mean, did NECC have any patient
4 prescriptions or did they make any patient
5 prescriptions?

6 A. Again, I'm not sure of your question.

7 Q. Well, were you and SSC ordering
8 prescriptions from NECC?

9 A. We were told that because NECC was licensed
10 as a pharmacy that they needed prescription names for
11 this order.

12 Q. They didn't need actual prescriptions.
13 They just needed names; correct?

14 A. Correct.

15 Q. Was that a red flag at all to you?

16 A. No, it was not.

17 Q. Why not?

18 A. I've been in medicine 38 years. A lot of
19 things have changed in 38 years. In 38 years we've
20 seen many, many, many changes and I thought this was
21 just another change in medicine.

22 Q. Are you aware of any other instance where
23 SSC had to give patient names to order medications?

24 A. I'm not aware of any.

25 Q. Did you personally review the Tennessee

1 how much time one took and how soon the next one could
2 be -- I'm sorry, let me withdraw the question.

3 If you had a busy day at SSC, how many
4 steroid injections would you do in a busy day?

5 A. Generally the maximum number would be 14.

6 Q. And were they scheduled a half hour apart?

7 A. Correct.

8 Q. Was there a reason for that?

9 A. That's my time schedule.

10 Q. And why did -- why do you allot 30 minutes
11 for an ESI?

12 A. That's because it's my comfortable time
13 schedule.

14 Q. How long does it take to tell if a steroid
15 injection is effective on the patient?

16 A. Typically one to two weeks.

17 Q. Do you have a practice for how often you
18 schedule steroid injections? For example, if someone
19 needs a second one, do they typically wait a certain
20 amount of time before they get the second one?

21 A. Yes, they do.

22 Q. And what is that time period?

23 A. Anywhere from three weeks to two and a half
24 months.

25 Q. Do they come in to see you in the office